4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-N-1287]

Actavis LLC, et al.; Withdrawal of Approval of Six Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of six abbreviated new drug applications (ANDAs) from multiple applicants. The applicants notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

FOR FURTHER INFORMATION CONTACT: Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993-0002, 240-402-6980, Martha.Nguyen@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The applicants listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process described in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

Application No.	Drug	Applicant
ANDA 202603	Methoxsalen Capsules, 10 milligrams (mg)	Actavis LLC, (an indirect, wholly owned subsidiary of Teva Pharmaceuticals USA, Inc.), 400 Interpace Pkwy., Bldg. A, Parsippany, NJ 07054
ANDA 205274	Amoxicillin Tablets, 125 mg and	Hikma Pharmaceuticals LLC, 1809

Application No.	Drug	Applicant
	250 mg	Wilson Rd., Columbus, OH 43228
ANDA 205513	Carisoprodol Tablets, 250 mg and 350 mg	Strides Pharma Global Pte. Limited, U.S. Agent, Strides Pharma Inc., 2 Tower Center Blvd., Suite 1102, East Brunswick, NJ 08816
ANDA 206410	Itraconazole Capsules, 100 mg	Do.
ANDA 207536	Flucytosine Capsules, 250 mg and 500 mg	Do.
ANDA 208227	Dutasteride Capsules, 0.5 mg	Do.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Approval of each entire application is withdrawn, including any strengths and dosage forms inadvertently missing from the table. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table that are in inventory on [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*], may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: December 7, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

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